No. 83-196

In the Supreme Court of the United States

OCTOBER TERM, 1983

WILLIAM D. RUCKELSHAUS, ADMINISTRATOR,
UNITED STATES ENVIRONMENTAL PROTECTION AGENCY,
APPELLANT

v.

MONSANTO COMPANY

ON APPEAL FROM THE UNITED STATES DISTRICT COURT FOR THE EASTERN DISTRICT OF MISSOURI

BRIEF FOR THE APPELLANT

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QUESTIONS PRESENTED

1. Whether Section 3(c)(1)(D) of the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA), 7 U.S.C. 136a(c)(1)(D) (which permits applicants to cite and EPA to consider in support of subsequent applications by other companies, health and safety data that were submitted to the government in support of initial applications for pesticide registration), works an unconstitutional taking of property requiring issuance of injunctive relief.

2. Whether Sections 3(c)(2)(A) and 10 of FIFRA, 7 U.S.C. 136a(c)(2)(A) and 7 U.S.C. 136h (which require EPA to disclose publicly health and safety data submitted to the agency in support of a pesticide registration application), are beyond Congress's power and constitute an unconstitutional taking of property warranting injunctive relief.

3. Whether the constitutionality of the arbitration scheme established in Section 3(c)(1)(D)(ii) of FIFRA, 7 U.S.C. 136a(c)(1)(D)(ii) (which provides that an original submitter of data or an applicant who cited that data may initiate binding arbitration if the parties fail to agree on the amount of compensation) is ripe for review, and, if so, whether the arbitration provision denies due process or amounts to an unconstitutional delegation of judicial power.

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OPINION BELOW

The opinion of the district court (J.S. App. 1a-37a) is reported at 564 F. Supp. 552.

JURISDICTION

The judgment of the district court (J.S. App. 39a-40a) was entered on April 12, 1983. An amended judgment (J.S. App. 41a-43a) was entered on May 9, 1983. The Administrator of the Environmental Protection Agency filed a notice of appeal to this Court on May 10, 1983 (J.S. App. 44a-46a). On July 1, 1983, Justice Blackmun extended the time for docketing the appeal to August 8, 1983. The Jurisdictional Statement was filed on August 5, 1983, and the Court noted probable jurisdiction on October 11, 1983 (J.A. 260). The jurisdiction of this Court rests on 28 U.S.C. 1252.

CONSTITUTIONAL AND STATUTORY PROVISIONS INVOLVED

The Fifth Amendment to the United States Constitution and the relevant portions of the Federal Insecticide, Fungicide, and Rodenticide Act, 7 U.S.C. 136 *et seq.*, are reprinted at J.S. App. 47a-57a.

STATEMENT

The court below declared unconstitutional several important provisions of the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA), 7 U.S.C. 136 *et seq.*, the federal legislation regulating the marketing and use of pesticides. As we will show, in enacting FIFRA Congress struck a measured balance between the need for increased competition and the need for innovation in the pesticide industry. In accomplishing these objectives, the statute also accommodates private industry's interest in protecting information and the public's interest in understanding the potential hazards of pesticide products.

Under FIFRA, persons seeking to market a pesticide product in the United States first must obtain a registration for the product from the Environmental Protection Agency (EPA). 7 U.S.C. 136a(a). Before issuing the registration, the Administrator of EPA must determine, *inter alia*, that the pesticide's use will not cause unreasonable adverse effects on the environment, taking into account the benefits as well as the risk to humans or the environment. 7 U.S.C. 136(bb), 136a(c)(5)(C)-(D). The Administrator bases this determination in part on test data submitted or cited by the applicant for registration, data that generally include information on the chemical nature and structure of the pesticide as well as test results on the potential dangers of the product.[1]

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[1] The health and safety data required for registration consist of the following major types of studies: (1) acute toxicity studies, which define how poisonous the pesticide is when ingested, inhaled, or applied to the skin or eyes; (2) chronic toxicity studies, which are used to determine if chronic exposure to the pesticide

The provisions struck down by the district court were designed to permit EPA to consider the health and safety data submitted by one applicant in support of the application of another company (the "data consideration provisions), 7 U.S.C. 136a(c)(1)(D); they also require EPA to disclose these data to qualifying members of the public (the "data disclosure" provisions), 7 U.S.C. 136a(c)(2)(A), 136h(b) and (d). This case, therefore, relates only to health and safety data; the case does not involve a company's confidential product formulas or manufacturing processes, which are protected from disclosure by the terms of the statute (7 U.S.C. 136h(d)). Moreover, the protections afforded by FIFRA are wholly distinct from rights to exclusivity that a company may enjoy under the patent laws.

1. Statutory and regulatory background

The past century has witnessed the transformation of American agriculture into a large-scale industry characterized by intensive cultivation of the land. A major factor in this change, as well as a contributor to marked improvements in productivity, has been the widespread use of pesticides to control weeds and crop damage caused by insects, disease and animals. See S. Rep. 92-838, 92d Cong., 2d Sess. 3-4, 6-7 (1972). Greater use of pesticides has brought not only the benefit of protecting crops and ensuring high yields, but also the risk of harm to humans and the environment. The recognition of this hazard has been reflected in federal regulation of pesticide use for nearly 75 years. In 1910, Congress passed the Federal

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will have any long-term health effects such as causing cancer or birth defects; (3) residue studies, which describe the level of the pesticide and its degradation products which remain in food products; (4) environmental chemistry studies, which are used to determine how much of the pesticide and its degradation products remain in the environment after application; and (5) fish and wildlife studies, which define how toxic the pesticide is to fish and wildlife which may be exposed to the pesticide after application in the environment. See J.S. App. 17a; 47 Fed. Reg. 53192-53221 (1982).

Insecticide Act, which made it unlawful to manufacture and sell insecticides that were adulterated or misbranded as defined by the statute. Ch. 191, 36 Stat. 331. The following decades brought dramatic growth in pesticide research and development, and the states began to regulate pesticides extensively, leading to the adoption in 1946 of a model state statute, the uniform Insecticide, Fungicide and Rodenticide Act. S. Rep. 92-838, *supra*, at 7; H.R. Rep. 313, 80th Cong., 1st Sess. 3 (1947).[2] These developments led to the enactment in 1947 of the more comprehensive Federal Insecticide, Fungicide, and Rodenticide Act. Ch. 125, § 3, 61 Stat. 166.

In order to assume greater control over the marketing and use of pesticides, the 1947 legislation provided for the registration of pesticides marketed in the United States. H.R. Rep. 313, *supra*, at 2-3. The Act required applicants for registration to submit to the Secretary of Agriculture certain information regarding the pesticide, including the label bearing the directions for use and the claims made for the product, and, "if requested by the Secretary," any test data underlying the claims on the label. § 4(a), 61 Stat. 167.[3] The legislation set general standards for the labeling of pesticide products, including a requirement for a poison label for substances acutely

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[2] The use of pesticides also became widespread in nonagricultural contexts. For example, pesticides, as defined by FIFRA (7 U.S.C. 136(u)), include household insecticides, lawn and garden pesticides, swimming pool chemicals, industrial pesticides, termite treatments, and fumigants.

[3] Section 3(a)(1) of the statute made it illegal to market an unregistered pesticide in interstate commerce. 61 Stat. 166. While the Secretary could initially refuse a registration by notifying an applicant that the application did not comply with the substantive requirements of the law, the applicant could then force the issuance of a registration merely by filing a protest ("protest registration"). § 4(c), 61 Stat. 168. In such a case, however, a registrant was subject to increased penalties for any subsequent conviction for offenses relating to matters about which the Secretary had warned the registrant. § 8(b), 61 Stat. 170.

toxic to humans and a requirement for directions and warnings that were judged to be necessary and adequate to protect the public and to prevent injury to humans, other animals and vegetation. §§ 2(u)(2)(c) and (d), 3(a)(3), 61 Stat. 165, 166. A product whose label did not meet these requirements was classified as misbranded and could not legally be sold in interstate commerce. § 3(a)(5), 61 Stat. 166.[4]

Thus, the 1947 legislation was primarily a licensing and labeling statute. The application for registration could include test data, although for many years only a limited amount of such data was required (J.S. App. 25a; J.A. 219-221). In addition, the Secretary of Agriculture was authorized to require the submission of a pesticide's formula, if he deemed it necessary. § 4(b), 61 Stat. 167. The 1947 Act specifically prohibited disclosure of "any information relative to formulas of products" (§§ 3(c)(4), 8(c), 61 Stat. 167, 170), but did not address the disclosure of health and safety data.[5] Nor did it address the possible consideration of such data by agency officials in processing a subsequent application for the same pesticide.

Mounting public concern over the long-term effects of pesticides led to further regulation. In 1954, Congress amended the Federal Food, Drug, and Cosmetic Act to regulate pesticide residues in food products. 21 U.S.C. 346a. Under these provisions no food products can be marketed legally if pesticide residues exceed established tolerances. 21 U.S.C. 331(a), 342(a)(2)(B) and 346a(a). Persons seeking to establish a tolerance must submit data disclosing, inter alia, the name, chemical iden-

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[4] In addition to these categories of misbranding, Congress declared a product misbranded if it was an insecticide, fungicide or herbicide that would be injurious to humans, other animals or vegetation "when used as directed or in accordance with commonly recognized practice." § 2(u)(2)(g), 61 Stat. 165-166.

[5] As a matter of practice, however, the Department of Agriculture did not publicly disclose any of this information.

tity and composition of the pesticide chemical, as well as reports on its safety. 21 U.S.C. 346a(d)(1).

In 1959, Congress amended FIFRA to extend regulation to new classes of substances that had come into common use: nematocides, defoliants, dessicants and plant regulators (Pub. L. No. 86-139, § 2, 73 Stat. 286). And in 1964, acting on the recommendation of a Presidential Scientific Advisory Committee, Congress eliminated "protest registration," see n.3, *supra*, providing instead for administrative and judicial review of a decision to refuse or cancel a registration for a pesticide found to be unsafe (Pub. L. No. 88-305, § 2, 78 Stat. 190; see S. Rep. 92-838, *supra*, at 8-9). In 1970, the Department of Agriculture's FIFRA responsibilities were transferred to the new Environmental Protection Agency. Reorganization Plan No. 3 of 1970, 35 Fed. Reg. 15623 (1970). These various changes were not sufficient to satisfy the increasing public concern, however, and in 1972 Congress enacted extensive changes in the regulatory scheme.

2. The 1972 Amendments

The comprehensive revision of FIFRA by Congress in 1972 included a number of measures to provide increased environmental protection. For the first time, the statute regulated the use of pesticides directly, as well as their labeling and marketing.[6] Congress extended the reach of the legislation to include pesticides made and sold within a single state (§§ 3, 12, 86 Stat. 979, 989-990) and added new provisions for review, cancellation and suspension of registrations (§ 6, 86 Stat. 984).[7] These amendments also

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[6] Pursuant to Section 12(2)(G) of the amended Act, it was unlawful to use a pesticide contrary to its labeling. 86 Stat. 990. In addition, the Administrator was authorized to register a pesticide for restricted use only. Section 3(d)(1), 86 Stat. 981. Under certain circumstances, application of a restricted use pesticide was required to be directed by persons certified as applicators under the statute. §§ 3(d)(1)(C), 4, 86 Stat. 981, 983.

[7] The statute also upgraded the enforcement mechanisms by requiring registration of pesticide-producing establishments and

supplied a new substantive criterion for registration, that the pesticide would not cause "unreasonable adverse effects on the environment" (§ 3(c)(5)(C)-(D), 86 Stat. 980-981).

In addition, Congress revamped the registration procedures and addressed the issues of consideration and disclosure of submitted data, which had generated considerable controversy. For many years after the passage of the 1947 Act, the Department of Agriculture required only limited health and safety data. J.S. App. 25a; J.A. 219-221. Advances in scientific knowledge and analytical techniques, however, led to more stringent requirements. In 1971, the pesticide industry told Congress that increasingly rigorous administrative criteria for registration had required them to submit more extensive, and costly, safety and health data. *Federal Pesticide Control Act of 1971: Hearings Before the House Comm. on Agriculture*, 92d Cong., 1st Sess. 331 (1971). See Def't Exh. DDD at 60. The Department of Agriculture (and later EPA) adopted the practice of considering data submitted by one company when reviewing subsequent applications by others for registration of the same or a similar pesticide. This practice was well known to the companies involved. During congressional consideration of the 1972 Amendments, the industry's trade association, the National Agricultural Chemicals Association (NACA), acknowledged that (*Federal Environmental Pesticide Control Act: Hearings Before the Subcomm. on Agricultural Research and General Legislation of the Senate Comm. on Agriculture and Forestry*, 92d Cong., 2d Sess., Pt. II, 245 (1972)):

> Under the present law registration information submitted to the Administrator has not routinely been made available for public inspection. Such informa-

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authorizing their inspection (§§ 7, 9, 86 Stat. 987, 988); by authorizing stop sale, use or removal orders for pesticides in violation of the Act (§ 13, 86 Stat. 991) and by providing for civil penalties in addition to criminal enforcement (§ 14, 86 Stat. 992).

tion has, however, as a matter of practice but without statutory authority, been considered by the Administrator to support the registration of the same or a similar product by another registrant.[8]

In the industry's view, this practice, coupled with proposals for public disclosure of health and safety data, would have had a negative effect on research and development. NACA asked Congress to create proprietary rights in the data in the form of a statutory right to exclusive use of the data for the purpose of registration. *Federal Pesticide Control Act of 1971: Hearings Before the House*

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[8] See J.A. 70-74. Although the court below found that the Department of Agriculture had a policy against considering data developed by one company to support another company's registration (J.S. App. 26a), this finding cannot undermine the basis upon which Congress legislated in 1972. Moreover, the evidence in this case refutes this finding. Testimony by employees who processed applications for registration established that they routinely depended on the knowledge that sufficient health and safety data had been generated to support a prior registration when they approved a subsequent application for the same or a similar chemical (J.A. 219-227, 228-230, 234-245). Indeed, the Department of Agriculture even published a list of those pesticides that would require no additional toxicological data for registration. The purpose of this publication, "Interpretation 18," was to facilitate subsequent registrations (J.A. 236-237, 240). The only contrary evidence in this case came from the prior testimony of two former Department of Agriculture officials. But that testimony was not only directly contradicted by that of Harold Alford, who was employed as an Assistant Director of the USDA Registration Division (J.A. 98-101), it also was rejected by the court in which it was originally introduced. See *Mobay Chemical Corp.* v. *Costle*, 517 F. Supp. 252 and 517 F. Supp. 254, 267 n.11 (W.D. Pa. 1981), aff'd, 682 F.2d 419 (3d Cir.), cert. denied, No. 82-241 (Nov. 8, 1982). The district court in *Mobay*, as well as every court (other than the court below) that has considered the matter, concluded that all previously submitted data were regarded by the Department of Agriculture and EPA as available for approving subsequent applications. *Chevron Chemical Co.* v. *Costle*, 641 F.2d 104, 109 (3d Cir.), cert. denied, 452 U.S. 961 (1981); *Amchem Products, Inc.* v. *GAF Corp.*, 391 F. Supp. 124, 128 (N.D. Ga. 1975), remanded 529 F.2d 1297 (5th Cir. 1976). Accordingly, the district court's contrary finding should be rejected as clearly erroneous.

Comm. on Agriculture, supra, at 331; J.A. 70-74, 81-82. The House passed such a restriction (H.R. 10729, 92d Cong., 1st Sess. § 3(c)(2)(D) (1971), over the objection of several Members that it was an unwarranted extension of patent protection and generally anticompetitive. H.R. Rep. 92-511, 92d Cong., 1st Sess. 69 (remarks of Rep. Foley), 72 (remarks of Rep. Dow) (1971); 117 Cong. Rec. 39978, 40034, 40061 (1971).

The Senate bill, as reported by the Senate Committee on Agriculture and Forestry, retained the exclusive use provision because the committee thought proprietary rights would encourage research. S. Rep. 92-838, *supra*, at 6. Other Senators strongly objected to the new proposal. They believed this change in the registration process would require wasteful duplication of testing and raise barriers to entry into the pesticide market that exceeded the protection provided by the patent laws. S. Rep. 92-970, 92d Cong., 2d Sess. 12 (1972). The Senate Committee on Commerce, to whom the bill was also referred, struck the exclusive use provision; this action was supported by the Department of Justice and EPA. *Id.* at 2, 12-13; S. Rep. 92-838 (Pt. II), 92d Cong., 2d Sess. 21 (1972).

This conflict in the Senate was resolved by a compromise that was intended to provide both an incentive for research and a means for maintaining entry of competitors into the market. S. Rep. 92-838, Pt. II, *supra*, at 69, 71-73. The two committees decided on a mandatory data licensing scheme under which EPA could consider studies submitted by one company in support of the application of another firm, so long as the second company offered to compensate the original data submitter. *Id.* at 71-73. The amount of compensation would be determined either through negotiation between the parties, or, if that failed, by EPA order subject to judicial review. Pub. L. No. 92-516, § 3, 86 Stat. 979. The compromise was accepted by the full Senate and acceded to by the House during the conference. H.R. Conf. Rep. 92-1540, 92d Cong., 2d Sess. 9, 31 (1972).

At the same time, Congress added a new Section 10 (86 Stat. 989) to govern public disclosure of data submitted in support of applications for registration. This provision allowed applicants to designate portions of submitted data as "trade secrets or commercial or financial information" and it prohibited EPA from publicly disclosing such information. Moreover, the data consideration provision (§ 3(c)(1)(D)) provided that any "trade secret" data that could not be publicly disclosed under Section 10 could not be considered by EPA at all to support another registration application, unless the original submitter consented. 86 Stat. 979. Thus, the data consideration/mandatory licensing scheme would apply only to data that fell outside the scope of "trade secret" protection under Section 10.

The 1972 Amendments, however, failed to define "trade secrets," and failed to specify an effective date. The latter question was resolved in 1975 when Congress amended Section 3(c)(1)(D) to provide that the mandatory licensing provisions applied only to data submitted on or after January 1, 1970. Pub. L. No. 94-140, 89 Stat. 751.[9] The definition of "trade secrets" was left to the EPA Administrator and the courts.

EPA maintained that in the 1972 and 1975 Amendments Congress had intended to give trade secret protection to only a narrow range of information—principally statements of formulas and manufacturing processes—that did not include health and safety data. Such data, therefore, could be disclosed to the public and could be

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[9] Section 3(c)(1)(D), as amended in 1975, was challenged by an original data submitter on the ground that Section 3(c)(1)(D) caused an unconstitutional taking of its property rights in the data it had submitted prior to January 1, 1970. This claim was rejected by a three-judge court, which held that Section 3(c)(1)(D) did not "take" any property rights. *Mobay Chemical Corp.* v. *Costle*, 12 Env't Rep. Cas. (BNA) 1572 (W.D. Mo. 1978). A direct appeal to this Court under 28 U.S.C. 1253 was dismissed on the ground that the three-judge court had been improperly convened. 439 U.S. 320 (1979).

considered by EPA in support of registration applications. In a series of lawsuits, data-submitting firms challenged EPA's interpretations and obtained several decisions holding that the "trade secret" prohibition in the 1972 Act applied to any data, including health and safety data, that met the expansive definition of "trade secret" set forth in the Restatement of Torts § 757 (1939). *E.g.*, *Chevron Chemical Co.* v. *Costle*, 443 F. Supp. 1024 (N.D. Cal. 1978); *Mobay Chemical Corp.* v. *Costle*, 447 F. Supp. 811 (W.D. Mo. 1978). As a result of these decisions, the "trade secret" prohibition in Section 10 operated to bar public access to much of the data on which EPA based its decisions to register pesticides and the corresponding prohibition in Section 3(c)(1)(D) allowed data-submitters to prevent any other firm from obtaining registrations for products that were the same or substantially similar to previously registered products unless the second firm duplicated the data supporting the first registration, or it was determined, after perhaps years of litigation, that particular items were not trade secrets. In part because of such "trade secret" controversies, "the process of registering new pesticides simply ground to a halt." *Chevron Chemical Co.* v. *Costle*, 499 F. Supp. 732 (D. Del. 1980), aff'd on other grounds, 641 F.2d 104, 111 (3d Cir.), cert. denied, 452 U.S. 961 (1981).[10] See H.R. Rep. 95-663, 95th Cong., 1st Sess. 18 (1977); S. Rep. 95-334, 95th Cong., 1st Sess. 3 (1977).

3. The 1978 Amendments

Faced with this breakdown in the registration program, Congress, in the Federal Pesticide Act of 1978 (1978 Amendments) (7 U.S.C. 136 *et seq.*), comprehensively revised the FIFRA data consideration and disclosure provisions. The 1978 Amendments abolished the

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[10] See generally, Schulberg, *The Proposed FIFRA Amendments of 1977: Untangling the Knot of Pesticide Registration*, 2 Harv. Envtl. L. Rev. 342 (1977).

1972 prohibition on agency consideration of "trade secret" data because it had operated to discourage small potential competitors from entering the market by requiring them to duplicate health and safety tests for products similar to those already registered.[11] Congress was concerned that FIFRA, in practice, acted as a de facto extension of patents beyond the statutory period of protection. See, *e.g.*, S. Rep. 95-334, *supra*, at 8, 30-31.

In order to promote competition and eliminate needless duplicative testing of pesticide chemicals like those already registered (see S. Rep. 95-334, *supra*, at 30-31), Congress established a new registration scheme. The costs of developing health and safety data are now spread among all beneficiaries of the data; at the same time, innovation incentives are provided by exclusive use and compensation provisions that are independent of whatever protections a company may have under the patent laws (*ibid.*). Under the 1978 Amendments, applicants are granted a 10-year period of exclusive use for data on new active ingredients contained in pesticides registered after September 30, 1978. § 3(c)(1)(D)(i), 7 U.S.C. 136a(c)(1)(D)(i). All other data submitted after December 31, 1969, may be cited and considered in support of another application for 15 years following the original submission, if the applicant offers to compensate the original submitter. § 3(c)(1)(D)(ii), 7 U.S.C. 136a(c)(1)(D)(ii). In these instances, the data are not disclosed to the latter applicant but are viewed only by

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[11] Most of the pesticide products for which registration is sought contain active ingredients that are also contained in previously registered products. Because the first registrant(s) of products containing a particular active ingredient normally will have supplied substantial amounts of health and safety data, EPA's files contain much data relevant to subsequent decisions whether to register other products containing the same ingredient. As the district court found, most of the testing and research is done by a few, relatively large firms, of which Monsanto is one (J.S. App. 4a).

EPA personnel.[12] The later applicant, in order to cite the data, must offer to compensate the original submitter; if the parties cannot agree on the amount of compensation, either may initiate binding arbitration proceedings.[13] Data that do not qualify for either the 10-year period of exclusive use or the 15-year period of compensation may be considered by EPA without limitation. § 3(c)(1)(D)(ii), 7 U.S.C. 136a(c)(1)(D)(iii). All of these provisions operate independently of the patent laws, so chemicals or products that are patented by the original data submitter may not be copied by other companies for 17 years (35 U.S.C. Supp. V) 154). Thus, the data consideration provisions come into play only when the chemical or product is not patentable or when patent protection has expired.

The 1978 Amendments also added a new provision, Section 10(d) (7 U.S.C. 136h(d)), that provides for disclosure of all health and safety data to qualified requesters.[14] This provision was designed to enable members of

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[12] The later applicant need not have, and usually will not have, obtained or seen a copy of the original submitter's data in order to cite the data in support of the application. EPA makes public lists of persons who have submitted data along with general descriptions of the information. Applicants may use these lists to determine what data to cite.

[13] The decisions of the arbitrator may be overturned for "fraud, misrepresentation, or other misconduct." 7 U.S.C. 136a(c)(1)(D)(ii).

[14] While Section 3(c)(2)(A) also requires the Administrator to make registration data available to the public, that Section is subject to Section 10, which specifically provides for the disclosure of the data at issue in this case. See 7 U.S.C. 136a(c)(2)(A), 136h(d)(1). For the purposes of this brief, references to Section 10 shall be deemed to include Section 3(c)(2)(A) as well. Under Section 10(d)(1), 7 U.S.C. 136h(d)(1), EPA must, on request, disclose to qualified requestors "[a]ll information concerning the objectives, methodology, results, or significance of any test or experiment performed on or with a registered or previously registered pesticide or its separate ingredients, impurities, or degradation products, and any information concerning the effects of

the public to assess for themselves the hazards posed by pesticide products and to participate in and evaluate EPA's registration decisions. See, *e.g.*, H.R. Rep. 95-663, 95th Cong., 1st Sess. 18 (1977); 123 Cong. Rec. 25711 (1977) (remarks of Sen. Kennedy). The same Section, however, prohibits EPA from disclosing information that would reveal "manufacturing or quality control processes" or certain details pertaining to "deliberately added" inert ingredients unless "the Administrator has first determined that disclosure is necessary to protect against an unreasonable risk of injury to health or the environment." In addition, Section 10(g), 7 U.S.C. 136h (g), generally prohibits EPA from disclosing data to representatives of foreign or multinational pesticide companies, unless the original submitter consents. § 10(g), 7 U.S.C. 136h(g).[15]

4. The proceedings below

In its complaint in this case (J.A. 15-28), Monsanto sought injunctive and declaratory relief from the operation of the data consideration provisions of Section 3(c)(1)(D), 7 U.S.C. 136a(c)(1)(D), and the disclosure provisions of Section 10, 7 U.S.C. 136h, and related Section 3(c)(2)(A), 7 U.S.C. 136a(c)(2)(A). Monsanto alleged that the data consideration provision, Section 3(c)(1)(D), constitutes a "taking" of property for a private purpose without just compensation, in violation of the Fifth Amendment, and that the data disclosure provisions, Sections 3(c)(2)(A) and 10, are beyond Congress's Commerce Clause powers and effectuate a taking

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such pesticide on any organisms or the behavior of such pesticides in the environment, including, but not limited to, data on safety to fish and wildlife, humans and other mammals, plants, animals, and soil, and studies on persistence, translocation, and fate in the environment, and metabolism."

[15] Most, if not all, of the major pesticide companies are multinational and therefore are precluded by this Section from obtaining such data. J.A. 208; J.S. App. 4a.

without just compensation in violation of the Fifth Amendment. The complaint further alleged that the arbitration scheme provided by Section 3(c)(1)(D)(ii) violates the company's due process rights and constitutes an unconstitutional delegation of judicial power.

Following a bench trial, the district court ruled in favor of Monsanto. The court concluded that the data consideration and disclosure provisions of FIFRA are beyond Congress's Commerce Clause powers and constitute an unconstitutional taking of property in violation of the Fifth Amendment. The court held that Monsanto has a state-protected property right (based on the trade secret definition in the Restatement of Torts § 757 (1939)) in the data it submits to EPA, which precludes EPA from considering Monsanto's data in support of another person's registration application or from disclosing the data publicly. Section 3(c)(1)(D), the court concluded, appropriates Monsanto's "fundamental right * * * to exclude" others from use of its property, furthers private rather than public purposes, and operates as an unconstitutional taking of Monsanto's property (J.S. App. 31a-32a). The court also found that FIFRA's disclosure provisions (§§ 3(c)(2)(A) and 10) "effectively destroy" Monsanto's property, adding that disclosure is "beyond Congress' regulatory powers" because the public interest is satisfied by EPA's analysis of the pesticide's hazards and by the labeling requirements under FIFRA (J.S. App. 32a-33a). The court further concluded that Congress had withdrawn the Tucker Act remedy, which would ordinarily provide Monsanto with "just compensation," on the ground that the compensation and exclusive use provisions of Section 3 (7 U.S.C. 136a) "were intended to be the sole compensation for any taking" (J.S. App. 35a). Finally, the court held (*id.* at 34a) that the data-compensation scheme established in Section 3 is unconstitutional because it does not provide "just compensation" and because it denies Monsanto "due process" and amounts to an unconstitutional delegation of

judicial power. The court recognized (J.S. App. 36a-37a) that every other court that had considered these issues had held FIFRA constitutional, but chose not to follow those decisions.

The district court enjoined EPA from implementing "in any manner, directly or indirectly," FIFRA Sections 3(c)(1)(D) and (2)(A), 10(b) and (d) (J.S. App 40a). In addition, it specifically enjoined "any use or consideration of or disclosure to any other person of any of [Monsanto's] information, research and test data, whenever submitted * * * unless [EPA] shall have first obtained [Monsanto's] express written permission" (*ibid.*). Both EPA and Monsanto moved to amend the judgment. EPA sought to clarify that the judgment did not preclude release of Monsanto's health and safety data to other agencies of the federal government or to Congress. EPA also moved for a stay pending appeal to this Court. Monsanto asked the court to add a new paragraph to the judgment specifying that EPA could process registrations for those manufacturers that can generate their own data or obtain the data from another manufacturer. On May 9, 1983, the district court issued an amended judgment that accommodated both EPA's and Monsanto's requests for amendment but denied EPA's motion for a stay (J.S. App. 41a-43a). EPA's subsequent motion in this Court for a stay pending appeal was denied. No. A-1066 (July 27, 1983) (Blackmun, Circuit Justice).

SUMMARY OF ARGUMENT

I. The statutory provisions that permit EPA to consider previously submitted data in reviewing later pesticide applications were enacted as part of a carefully crafted scheme designed to achieve two principal objectives: to assure the safety and efficacy of potentially hazardous pesticides and to promote competition in the industry. Since the time and expense involved in performing the requisite health and safety tests could act as a

barrier to entry, discouraging less affluent firms from reaching the market, Congress struck a legislative balance. While the predicate testing remains essential to the initial approval of a pesticide, it was deemed unnecessary to require these tests to be duplicated for subsequent registrations of products with the same or similar composition. In this way, the need to preserve public health and safety standards was accommodated with the desire to avoid the adverse economic impact of forcing potential competitors to reinvent the wheel for each product. At the same time, Congress afforded some incentives for innovators. First, the innovator retains the protection of the patent laws where applicable: his invention may not be copied for 17 years. Second, FIFRA provides a period of exclusive use and a scheme of compensation for original data submitters, so that certain information cannot be relied upon by potential competitors for 10 years and when such reliance is available the innovator may be compensated for his testing expenses.

Substantial public policies similarly underlie the data disclosure provisions. While confidential product formulas and manufacturing practices cannot be disclosed, FIFRA allows qualified members of the public to obtain certain health and safety data. Such disclosure may not be made to representatives of multinational companies, a restriction that bars access to most, if not all, of Monsanto's competitors in the research and development of pesticides (J.S. App. 21a). The disclosure that is permitted allows interested members of the public to participate in the agency decisionmaking process and affords the opportunity to assess in a meaningful way the risks attendant upon pesticide use.

In light of the public purposes advanced by this regulatory scheme, the district court erred in concluding that these provisions of FIFRA exceed Congress's power under the Commerce Clause to regulate the pesticide industry.

II. A. The district court was also incorrect in ruling that FIFRA's data consideration and disclosure provi-

sions constitute a taking of property in violation of the Fifth Amendment. Although it correctly determined that Monsanto did not possess a federally-created property interest in its health and safety data, the court nevertheless found that such a right existed under Missouri law. The court's analysis is flawed. First, the court failed to recognize that whatever rights Monsanto held prior to the time it submitted data to EPA, those rights became subject to the federal regulatory scheme when Monsanto chose to make its submissions in order to obtain commercially valuable pesticide registrations. Second, because the challenged provisions are part of a comprehensive and uniform federal scheme regulating the use of data submitted pursuant to that scheme, state laws are preempted to the extent that they are in irreconcilable conflict with the functioning of that scheme. And, even if state law continues to govern, the court misconstrued the limited protection afforded by state trade secrecy law.

Accordingly, Monsanto retained no cognizable property interest under the Fifth Amendment in the health and safety data it submitted to EPA, and that is dispositive of its Fifth Amendment claim.

B. Even if it is determined that Monsanto retained a protected property interest, FIFRA does not cause a "taking" of property within the meaning of the Fifth Amendment. When the nature of the government action, and the strong public policies it fosters, is weighed against the limited impact on Monsanto (which retains significant rights and benefits), it is clear that no taking has occurred. Monsanto's assertions boil down to nothing more than unilateral expectations of competitive advantage flowing from the federal regulatory scheme itself. This provides no foundation for a taking claim.

III. Since, in our view, no taking has occurred, the Court need not reach Monsanto's remaining contentions. But even if FIFRA is deemed to cause a taking of property, the district erred in granting injunctive relief. Where, as here, EPA's actions are authorized by statute

and serve an important public purpose, the only remaining issue relating to the availability of injunctive relief is whether just compensation will be provided. While FIFRA affords Monsanto a measure of compensation from private parties who seek to rely on the data consideration provisions in obtaining "me-too" registrations, a claim against the government for just compensation remains available under the Tucker Act, 28 U.S.C. 1491, since Congress evinced no intent to withdraw that remedy. The district court's conclusion to the contrary is incorrect.

IV. The district court should not have entertained Monsanto's attack on the arbitration and compensation scheme in Section 3(c)(1)(D)(ii). This issue is not ripe for adjudication because Monsanto has not yet been involved in the arbitration process. Thus, the question is hypothetical at this point and any disposition would be merely advisory. Should Monsanto later have occasion to proceed through the arbitration scheme, and should it be dissatisfied with the result, it could seek judicial relief.

In any event, the arbitration and compensation scheme fully satisfies the standards established by this Court, and thus offends neither the Due Process Clause nor Article III. Indeed, it is quite similar to other adjudicatory mechanisms this Court has upheld for the determination of statutorily-created rights.

ARGUMENT

I. FIFRA'S DATA CONSIDERATION AND DISCLOSURE PROVISIONS ARE PLAINLY WITHIN THE AUTHORITY OF CONGRESS TO REGULATE INTERSTATE COMMERCE

Although the district court acknowledged that Congress's purpose in enacting the data consideration and disclosure provisions was to promote competition in the marketplace and to vindicate the public's right to information about the harmful effects of pesticide products (J.S. App. 13a-14a, 17a), the court incorrectly concluded that these statutory provisions were beyond the authority

conferred on Congress by the Commerce Clause of the Constitution (J.S. App. 32a-34a, 39a). The court did not, and could not, hold the pesticide industry immune from congressional regulation on the ground that it does not engage in or affect interstate commerce. Rather, the court simply disagreed with Congress's policy judgment that the particular statutory provisions at issue serve the public interest. But it is Congress, rather than the courts, that is empowered by the Commerce Clause to determine what regulation of the manufacture and use of pesticides will promote the public health and welfare.

It is, for example, long established that Congress may properly act "to prevent the flow of commerce from working harm to the people of the nation." *Mulford* v. *Smith*, 307 U.S. 38, 48 (1939). And this Court has held on many occasions that there need only be some rational basis for congressional action in order to sustain an exercise of the plenary authority granted to Congress by the Commerce Clause. See, *e.g.*, *United States* v. *Darby*, 312 U.S. 100, 121 (1941). More particularly, this Court has consistently upheld, as authorized by the commerce power, federal legislation regulating business competition or activities causing potential environmental damage, the two primary purposes served by the statutory provisions at issue here. *Hodel* v. *Indiana*, 452 U.S. 314, 329 (1981); *Hodel* v. *Virginia Surface Mining & Reclamation Ass'n*, 452 U.S. 264, 282 (1981); *Bowman Transp., Inc.* v. *Arkansas-Best Freight System, Inc.*, 419 U.S. 281, 298 (1974); *Northern Securities Co.* v. *United States*, 193 U.S. 197, 337-338 (1904).

Nor is it unusual for Congress to require, as a condition of participating in commerce, that persons supply information to federal agencies that they might otherwise choose not to disclose. For example, firms seeking to sell securities to the public (15 U.S.C. 77aa, 77eee(c)), to manufacture or sell pharmaceuticals (Federal Food, Drug, and Cosmetic Act, 21 U.S.C. 355(a), (b) and (j); 21 U.S.C. 360(j); 21 C.F.R. 314.1), to acquire another

company (Hart-Scott-Rodino Antitrust Improvements Act of 1976, 15 U.S.C. 18a; 16 C.F.R. 803.1), or to secure a government procurement contract (10 U.S.C. 2313(b); 42 U.S.C. 254(c)) are subject to reporting or records access requirements. The data thus obtained become part of the pool of information available to the recipient federal agency in conducting its business. And, in certain circumstances, such information is available to persons outside the government (*e.g.*, 15 U.S.C. 77f(d); 21 U.S.C. 360(f); 21 U.S.C. 379; 5 U.S.C. 552). This familiar method of regulating commerce is particularly suitable to the manufacture and marketing of potentially hazardous substances such as pesticides.

A. The data consideration provisions

From the beginning of its consideration of the appropriate use by EPA of data submitted by pesticide registrants, Congress has been concerned with the statute's impact on the competitive structure of the pesticide industry. Although in 1972 the Senate Committee on Agriculture and Forestry wanted to grant exclusive proprietary rights to data submitters, S. Rep. 92-838, *supra*, at 6, the Committee on Commerce was concerned that such a provision would raise undesirable barriers to entry in the pesticide market and that it would also compel unnecessarily duplicative expenditures for testing similar products. S. Rep. No. 92-970, *supra*, at 12.[16] The compromise struck by the two committees, which then became law, provided for mandatory licensing, with compensation, of

[16] S. Rep. 92-970, *supra*, at 12, states:

> In effect, whether or not a pesticide has patent protection, a manufacturer wishing to register a pesticide previously registered would have to duplicate the required test data. As patent protection is granted to a substantial number of pesticides, this provision of the bill imposes requirements on subsequent producers beyond the licensing fees that a patent-holder may receive. In the extreme, a monopoly in the production of a pesticide could ensue if competitors are unable to afford the sometimes costly safety and efficacy tests.

testing data previously submitted. By providing for reliance by other companies on the data and the sharing of costs, Congress was plainly acting on its conclusion that data submitters should not have the monopoly benefits of an exclusive use provision. In addition, Congress intended to avoid the "wasteful, time-consuming, and costly process" of requiring subsequent applicants to reinvent the wheel in order to market a previously approved product. S. Rep. 92-838 (Pt. II), *supra*, at 72-73.

As noted above, see page 11, *supra*, judicial interpretations of the trade secrets provision of the 1972 Amendments had thwarted Congress's intent to assure a competitive market for pesticides and to promote the efficiency of the registration process. In 1977, the House Committee on Agriculture recognized that the lack of clarity in the 1972 legislation had spawned litigation that had brought the registration process to a standstill. H.R. Rep. 95-663, *supra*, at 18. In the Committee's view, it was Congress's task to strike (*ibid.*):

> a careful balance between the interests of the small formulator and the need for encouraging competition in the pesticide business, on the one hand, and the need to assure the continued research and development of new pesticides * * *.[17]

The Senate was equally concerned with the impact of the 1972 Amendments on competition. S. Rep. 95-334, 95th Cong., 1st Sess. 3-4 (1977). The Committee on Agriculture, Nutrition and Forestry found there were about 400 manufacturers of basic pesticide chemicals, but that there were only some 40 firms that engage in the development of new pesticide products and that normally generate the health and safety data necessary for registration (*id.* at 27). In addition, there are thousands of

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[17] The House bill proposed to achieve that balance by generally providing for a five-year exclusive period followed by a five-year compensation period for test data. H.R. 8681, 95th Cong., 1st Sess. § 2a (1977). See H.R. Rep. 95-663, *supra*, at 18.

small firms that buy pesticide chemicals for formulation into end-use products but that do little, if any, of the costly testing necessary to obtain a registration. *Id.* at 28. See *id.* at 34 (study prepared by Office of Pesticide Programs, EPA). The Committee noted (*id.* at 30-31) (emphasis added):

> The current law in essence treats every firm in exactly the same way and every registration as an autonomous entity. *This has resulted in duplication of costs and significant reduction in competition.* This was not the intent of the Congress in passing the 1972 amendments. Unfortunately, it is the result.
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> * * * * *
>
> The amendments also avoid an extension of the patent rights on chemicals. More importantly, these amendments eliminate FIFRA's most severe regulatory impact on the industry—the anti-competitive effects of *de facto* "exclusive use." [18]

It is apparent, then, that Congress reasonably viewed the costs associated with duplicating health and safety data as a significant barrier to entry into the pesticide market, and that its efforts to diminish this barrier effect were rationally related to its objective of fostering competition. See *Hodel* v. *Virginia Surface Mining & Reclamation Ass'n*, 452 U.S. at 282; *Bowman Transp., Inc.* v. *Arkansas-Best Freight System*, 419 U.S. at 298; *United States* v. *Darby*, 312 U.S. 100, 121 (1941).

The district court, ignoring the careful balance Congress struck, instead made its own assessment of the effect of the data consideration provisions and its own

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[18] To achieve these ends, the Senate Committee recommended no restriction on the consideration of test data by EPA for other applications, but provided a right of compensation for seven years after the submission of the data. S. Rep. 95-334, *supra*, at 7-8. The conference committee, departing from both the Senate and the House versions, settled on the scheme set out in Section 3(c)(1)(D), 7 U.S.C. 136a(c)(1)(D). S. Conf. Rep. 95-1188, 95th Cong., 2d Sess. 29-31 (1978).

determination of the competitive structure of the industry. Because it concluded that Monsanto's competitors would benefit from the statute, the court found that only private, rather than public, purposes were served by the legislation (J.S. App. 32a). That is not factually or legally accurate. Almost any effort to foster competition is likely to have the effect of benefitting potential competitors, but that fact does not diminish the public nature of the benefits that accrue from increased competition. Moreover, it is well within Congress's powers to employ a regulatory scheme that benefits private persons as a means of achieving its legitimate purposes. *Berman* v. *Parker*, 348 U.S. 26, 32-34 (1954). The district court's view that Congress had misjudged the extent of competition in the pesticide industry provided no legitimate basis for overturning the congressional exercise of the commerce power. The legislative history shows that Congress had an adequate basis for concluding that an exclusive use provision (prohibiting EPA from considering prior data in support of subsequent applications) would have undesirable anticompetitive effects. Plainly, the court below erred in displacing Congress's judgment in favor of the court's own view of the matter. *Hodel* v. *Indiana*, 452 U.S. at 326. Lastly, the court ignored Congress's express desire to eliminate unnecessary duplicative testing as a means of promoting an efficient and effective registration scheme. See S. Rep. 95-334, *supra*, at 3-4, 7. This provides an independent basis, apart from the desire to encourage competition, for the data consideration provisions.

B. The data disclosure provisions

Congress's decision to provide for the disclosure of health and safety data is also a legitimate exercise of the commerce power. Congress repeatedly declared that the potential hazards of pesticide use justified recognition of the public's right to complete information on the safety and efficacy of these items of commerce. S. Rep. 95-334, *supra*, at 4, 13; H.R. Rep. 95-663, *supra*, at 18-19, 42.

Disclosure of this information allows members of the public to decide whether and how to use these often inherently dangerous products. The release of this information also informs the public of the basis of EPA's decision to permit the product to be put on the market, and facilitates the public's participation in proceedings under the Act.[19] See *National Fertilizer Association* v. *Bradley*, 301 U.S. 178 (1937); *Corn Products Refining Co.* v. *Eddy*, 249 U.S. 427, 431 (1919).

The district court concluded, however, that the public need only rely on EPA's decision to register the product and that the public does not require any more information than what is found on the label (J.S. App. 33a). Once again the court impermissibly substituted its judgment for that of Congress. *Hodel* v. *Indiana*, 452 U.S. at 326. Moreover, as the district court itself noted (J.S. App. 24a), the label does not provide complete information (J.A. 213-214, 231-232). Neither the label nor the fact EPA has registered the product supplies a basis for understanding or evaluating EPA's conclusion that the product will not cause unreasonable adverse effects on the

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[19] As the district court found (J.S. App. 22a), because of the health and safety significance of the data submitted in support of an application for a pesticide registration, EPA often receives requests for access to this information from environmental organizations interested in protecting humans and the environment from the adverse effects of these pesticide chemicals, from farmworker unions that serve to protect the interest of farmworkers who are directly exposed to the pesticides used in the fields where they work, and from union groups that represent the chemical workers who manufacture pesticides (J.A. 249-250, 251-252). Moreover, FIFRA specifically provides for public participation in EPA's decisionmaking process. Members of the public may petition EPA to take regulatory action. See 7 U.S.C. 136a. They may comment in rulemaking proceedings and on other regulatory actions. See, *e.g.*, 7 U.S.C. 136a(b). And they may petition for the commencement of, and participate in, administrative hearings to cancel or deny a pesticide registration. See, *e.g.*, 7 U.S.C. 136d(d); 40 C.F.R. 164.31.

environment.[20] See 7 U.S.C. 136a(c)(5) and (7). Thus, there was ample reason for Congress to rely here on the desirability (recognized by this Court in other contexts) of facilitating public participation in regulatory decisions by making information available to the public. See, *e.g.*, *FCC* v. *Schreiber*, 381 U.S. 279 (1965); *Utah Fuel Co.* v. *National Bituminous Coal Comm'n*, 306 U.S. 56, 60-62 (1939). Consequently, the district court erred in holding that Congress exceeded its authority by permitting disclosure of safety and health data.

II. FIFRA'S DATA CONSIDERATION AND DISCLOSURE PROVISIONS DO NOT TAKE PROPERTY IN VIOLATION OF THE FIFTH AMENDMENT

A. An interest in preserving the exclusive use and secrecy of health and safety data required under FIFRA does not qualify as property protected by the Taking Clause of the Fifth Amendment

The district court's declaration that Sections 3(c)(1)(D) and 10 of FIFRA are unconstitutional rested in part on its determination that Monsanto had an interest in its health and safety data that qualifies as property under the Taking Clause of the Fifth Amendment. Although the court properly rejected Monsanto's claim of a federally-created property right in these data, it accepted the contention that Monsanto has an interest created and protected by state law in maintaining the secrecy and exclusive use of these data and that this interest is property protected by the Fifth Amendment (J.S. App. 29a-30a). The district court found (*ibid.*) a basis for this right in Missouri law, which provides a right to pro-

[20] This determination requires the Administrator to assess the "risk to man or the environment, taking into account the economic, social, and environmental costs and benefits of the use of any pesticide." 7 U.S.C. 136(bb). Of necessity, this determination is a generalized one that will not always apply to every individual instance of the use of a pesticide. A member of the public, therefore, may well have need of the underlying data to evaluate the risk of individual exposure. J.A. 213-14.

tect trade secrets based on the Restatement of Torts § 757 (1939). See *Sandlin* v. *Johnson*, 141 F.2d 660 (8th Cir. 1944).

1. Even if the district court were correct in concluding that Monsanto possessed trade secret protection under state law, that finding would not be dispositive of the issues in this case. We start from the common ground that while the data remained exclusively in Monsanto's hands any trade secrets contained in the data would enjoy whatever protections state law afforded. But when Monsanto chose to reveal the data to EPA in exchange for commercially valuable pesticide registrations, it accepted the conditions attendant upon issuance of the registrations. In *Kewanee Oil Co.* v. *Bicron Corp.*, 416 U.S. 470 (1974), this Court held that state trade secret laws are not preempted as a general matter by the federal patent laws, but the decision acknowledges that Congress possesses the power to supersede such state laws. *Id.* at 493. Where, as here, Congress has plainly rejected the expansive definition of "trade secrets" contained in the Restatement and has prescribed a uniform procedure for processing registration data, it would contravene the Supremacy Clause for state law to "'stand[] as an obstacle to the accomplishment and execution of the full purposes and objectives of Congress.'" *Id.* at 479 (quoting *Hines* v. *Davidowitz*, 312 U.S. 52, 67 (1941)). See *Hancock* v. *Train*, 426 U.S. 167, 179-180 (1976).[21]

FIFRA comprehensively defines the rights and obligations of EPA with respect to submitted health and safety data. It does so in a manner that necessarily preempts

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[21] The fact that the Court has held that the federal patent laws have not preempted state trade secret laws, *Kewanee Oil Co.* v. *Bicron Corp.*, *supra*, does not control the preemption question under FIFRA. In *Kewanee*, this Court had to examine the objectives of the patent and trade secret laws for irreconcilable conflict because the patent law does not explicitly address the role of trade secrets. 416 U.S. at 480. In FIFRA, Congress has specifically addressed this question and clearly intended to prescribe uniform rules with respect to the use of pesticide registration data.

conflicting state laws. Indeed, the proper functioning of the registration scheme depends upon uniform application to all data; it cannot, nor did Congress intend it to, vary depending on whether data are submitted from a Missouri company or a firm based in another state. As a result, any continuing right to confidentiality in the data Monsanto submitted to EPA is solely a question of federal law. *Chevron Chemical Co.* v. *Costle*, 641 F.2d 104, 116 (3d Cir.), cert. denied, 452 U.S. 961 (1981).

Moreover, the dominance of federal authority in this area is especially strong because the statute defines the duties of a federal agency and its employees. As this Court has held, state law rules cannot regulate the functions of the United States without its consent. *EPA* v. *California*, 426 U.S. 200, 211 (1976); *Hancock* v. *Train*, *supra*, 426 U.S. at 178; *United States* v. *Georgia Public Service Commission*, 371 U.S. 285, 293 (1963); *United States* v. *County of Allegheny*, 322 U.S. 174, 183 (1944).[22]

2. In addition to its error in relying on Missouri law, the district court was also incorrect in finding that FIFRA contravenes the objectives of trade secret protection under state law. The district court relied on the Restatement of Torts definition of "trade secrets," as "any formula, pattern, device or compilation of information which is used in one's business, and which gives him an opportunity to obtain an advantage over competitors who do not know or use it." *Id.* § 757, comment b. The protection afforded by law to this interest is significantly limited, however, since the basis of liability to the trade secret owner is the breach of a general duty of good faith. *Id.* at comment a. Thus, one who discloses or uses trade secret information is liable to the owner only if there is

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[22] Congress's practice of setting the exclusive standard for disclosure of information submitted to federal officials has a lengthy history. The Trade Secrets Act, 18 U.S.C. 1905, prohibits disclosure by federal officials "to any extent not authorized by law." That statute was enacted in 1948 as a codification of earlier laws. See *Chrysler Corp.* v. *Brown*, 441 U.S. 281, 294-298 (1979).

some impropriety associated with the acquisition of the secret (*e.g.*, a breach of a contractual obligation or a breach of confidence arising from a relationship such as that between an employer and employee). *Id.* § 757. As this Court has recognized, one policy underlying the law of trade secret protection is the need to maintain recognized standards of commercial ethics, *Kewanee Oil Co.* v. *Bicron Corp.*, 416 U.S. at 481, and therefore protection is provided only when those standards have been breached.[23] This unique characteristic of the legal protection provided to trade secrets has led this Court to recognize that the interest of a trade secret owner should not be analyzed as property in the traditional sense. *E.I. Du Pont de Nemours Powder Co.* v. *Masland*, 244 U.S. 100, 102 (1917) (Holmes, J.). Indeed, the Restatement of Torts, relied on by Monsanto and the district court, also concludes that the interest of a trade secret owner is not a property interest but merely an interest in ensuring the maintenance of ethical business dealings. *Id.* § 757, comment a. Thus, any protection is based exclusively on the legal obligations of the particular persons who obtain the secret and therefore have the power to disclose or use it. As we have shown, in this case it is federal law (prescribed in detail by Congress) rather than state law that is the source of these obligations.[24]

3. The simple fact remains that whatever protections were available to Monsanto prior to its submission of data

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[23] In this respect, then, trade secret protection differs significantly from the benefits accruing to the holder of a patent; the patentee's right to exclude the use of the invention runs "against the world," and liability for infringement does not depend on a breach of good faith. See *Kewanee Oil Co.* v. *Bicron Corp.*, 416 U.S. at 489-490; 35 U.S.C. (Supp. V) 154.

[24] Indeed, the Restatement of Torts explicitly recognizes that a person may have a privilege to disclose or use a trade secret and that such a privilege may be created by law "in order to promote some public interest" (*id.* § 757, comment d). Thus, disclosure or use of a trade secret pursuant to a federal law would be privileged conduct under the rule relied on by Monsanto and the district court.

to EPA, it chose to forgo them in order to obtain registrations. Monsanto cannot properly contend that the history and administration of FIFRA created any reasonable expectation to the contrary. Prior to the 1972 Amendments, there were no statutory provisions regarding the consideration of previously submitted data in support of another application for registration. Contrary to the views of the district court, the practice of the Department of Agriculture (and EPA when it took over the administration of the program in 1970) was to grant subsequent "me-too" registrations for pesticides without requiring the duplication of supporting data that had been previously submitted.[25]

The desire to change prior practice and to offset the increasing cost burden of producing registration data was the basis for the industry's request to Congress in 1971 for a right to exclusive use of health and safety data submitted in support of a registration. This proposal was opposed by members of Congress, the Department of Justice, and EPA, who were concerned that an exclusive-use provision would have undesirable anticompetitive effects and force wasteful duplication. S. Rep. 92-970, *supra*, at 12-13; S. Rep. 92-838 (Pt. II), *supra*, at 12-13, 69. The compromise reached by Congress provided for compensation to a data submitter when its data were considered by EPA in connection with another application. Thus, contrary to the hopes of Monsanto and some other companies, the 1972 Amendments did not provide for a right of unlimited exclusive use and did not, as a general matter, prohibit EPA from considering previously submitted data.

In enacting these changes, however, Congress excluded from the use and compensation scheme all data that were

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[25] As shown above, see page 8 & note 8, *supra*, the record here is so overwhelming on this point that the district court's contrary finding must be deemed clearly erroneous. This Court is not precluded by its Rule 15.1(a) from rejecting this determination, since the legal question whether the 1978 Amendments took property within the meaning of the Fifth Amendment fairly comprises the subsidiary question of the reasonableness of Monsanto's expectations in 1972.

protected from disclosure by Section 10(b) as a trade secret, a term that was not defined by the statute. The 1978 Amendments represent Congress's attempt to rectify the situation created by judicial decisions interpreting the term "trade secret" in the 1972 Amendments in an overly broad manner (see pages 11-13, *supra*). It is evident from this history that far from possessing a long-standing, investment-backed expectation in preventing the use of health and safety data to approve registrations of other companies, the pesticide industry experienced a period when data requirements were less rigorous and when subsequent registrations were commonly based on another company's data; then, when the cost of producing such data increased significantly, the industry sought from Congress compensating benefits for its efforts. To the extent Congress rejected this request, it is plain that Congress defeated only a "unilateral expectation * * * [and] not a property interest entitled to protection" under the Fifth Amendment. *Webb's Fabulous Pharmacies, Inc.* v. *Beckwith*, 449 U.S. 155, 161 (1980). It is on this basis that the Third Circuit has rejected the contention that a data submitter under FIFRA has any property interest protected by the Fifth Amendment. *Mobay Chemical Corp.* v. *Gorsuch*, 682 F.2d 419, 423 (3d Cir.), cert. denied, No. 82-241 (Nov. 8, 1982); *Chevron Chemical Co.* v. *Costle*, 641 F.2d 104, 116, cert. denied, 452 U.S. 961 (1981).

The principal value of the data to Monsanto is the competitive advantage derived from obtaining a registration. But the ultimate source of that value is not the effort and money expended by Monsanto but the legislative decision to create a licensing scheme, which created the potential for an economic advantage in having a registration. Even though the result of that decision may have been to generate expectations of competitive gain, Congress has the unfettered power to adjust the consequences of its decision (or even to rescind the registration requirement altogether), as this Court has recognized. In *Reichelderfer* v. *Quinn*, 287 U.S. 315 (1932), the Court rejected the contention that neighboring landowners had a property right

in the continued dedication of land taken to establish Rock Creek Park in the District of Columbia. As the Court noted (287 U.S. at 319):

> Beyond the traditional boundaries of the common law only some imperative justification in policy will lead the courts to recognize in old values new property rights. * * * The case is clear where the question is not private rights alone, but the value was both created and diminished as an incident of the operations of the government. For if the enjoyment of a benefit thus derived from the public acts of government were a source of legal rights to have it perpetuated, the power of government would be exhausted by their exercise.

Since Monsanto's expectations, no matter how strong, were created as an incident to "the public acts of government," there is no warrant to accord them the status of a property interest protected by the Taking Clause.

The same is true with respect to the data disclosure provisions. The data submitted under FIFRA prior to 1972 were generally not disclosed to the public, although the statute itself expressly protected only product formulas, see page 5 & note 5, *supra*. Notwithstanding any expectation that may have arisen, the 1978 Amendments requiring disclosure do not defeat an interest of independent significance. As the district court found, the data are generated primarily for registration purposes (J.S. App. 21a); the competitive edge lies in the contribution the data make to obtaining a registration. But the statute specifically provides for the circumstances under which a particular company's data may or may not be considered, and these provisions operate independently of any authority to disclose the information. We have shown that Monsanto may not depend on its unilateral expectations to upset these rules, and in these circumstances, disclosure or nondisclosure no longer functions to control the primary business use of the data. There remains, then, no basis for concluding that the continued secrecy of this information is a substantial property interest protected by the Fifth Amendment.

B. Even if Monsanto does possess a protected property right in its test data, the 1978 Amendments are not a taking of that interest

Even if this Court were to conclude that Monsanto's expectations in controlling the use and disclosure of its data amounted to a protected property interest, the operation of the 1978 Amendments do not "take" this property within the meaning of the Fifth Amendment. Although this Court has on many occasions considered whether a governmental action constituted a taking, no simple formula for adjudging such claims has been established. *Penn Central Transp. Co.* v. *New York City*, 438 U.S. 104, 123-124 (1978). The essence of the inquiry is a weighing of the private interests against the public interest to determine if "justice and fairness" require the government to compensate for the economic injuries caused by governmental action. *Agins* v. *City of Tiburon*, 447 U.S. 255, 260-261, 262-263 (1980); *Andrus* v. *Allard*, 444 U.S. 51, 66 (1979); *Penn Central*, 438 U.S. at 124.

Among the factors to be considered in any particular case , the economic effect on the claimant, specifically the extent to which the government's action interferes with "distinct investment-backed expectations." *Penn Central*, 438 U.S. at 124. An important consideration is whether the regulation destroys all property rights or renders the claimant unable to derive any economic benefit from the property. *Andrus* v. *Allard*, 444 U.S. at 65-67. "[W]here an owner possesses a full 'bundle' of property rights, the destruction of one 'strand' of the bundle is not a taking, because the aggregate must be viewed in its entirety." *Id.* at 65-66.

Equally important, however, is the nature of the government action, since interference caused by a "public program adjusting the benefits and burdens of economic life to promote the common good," in contrast to a physical invasion or appropriation of property, more readily passes constitutional muster. 444 U.S. at 65-66. The

Court, after weighing the public interest and the public purposes served by the alleged taking, has sustained government actions that have had the effect of destroying or severely affecting property interests. *Goldblatt* v. *Hempstead*, 369 U.S. 590 (1962) (ordinance that effectively prohibited continuation of pre-existing business of sand and gravel mining); *United States* v. *Central Eureka Mining Co.*, 357 U.S. 155, 166-168 (1958) (government order prohibiting operation of private gold mines for two years); *Miller* v. *Schoene*, 276 U.S. 272, 279 (1928) (government order to destroy cedar trees that threatened to inflict disease on nearby commercial apple orchards). When tested against the standards developed and applied by this Court, Monsanto's claim of a taking must be rejected, as it has been by every court other than the court below that has considered the question. See *Mobay Chemical Corp.* v. *Costle*; *supra*,; *Pennwalt Corp.* v. *Gorsuch*, No. 80-2400 (W.D. Pa. July 23, 1982), aff'd as a companion case in *Mobay*, *supra*; *Chevron Chemical Co.* v. *Costle*, 499 F. Supp. 732 (D. Del. 1980), aff'd on other grounds, 641 F.2d 104 (3d Cir.), cert. denied, 452 U.S. 961 (1981); *Petrolite Corp.* v. *EPA*, 519 F. Supp. 966 (D. D.C. 1981). See also *Union Carbide Agricultural Products Co.* v. *Costle*, 632 F.2d 1014 (2d Cir. 1980), cert. denied, 450 U.S. 996 (1981).

1. The data consideration provisions

Section 3(c)(1)(D) defeats Monsanto's claimed expectation that it would retain control of the exclusive use of its health and safety data. As we have shown (pages 31-32, *supra*), these expectations do not provide a foundation for a taking claim. Moreover, the district court found that despite the enactment of the 1978 Amendments, Monsanto continues to expand its research and development and to submit data to EPA (J.S. App. 21a; J.A. 106, 213). Thus, even if these expectations technically qualify as a property interest, they are so insubstantial that even their total destruction should count for little

when reckoned against the public interest served by the legislation.

In addition, there is, of course, no physical invasion as might be the case with real property, but there is also no appropriation of Monsanto's property by the government. The government does not market pesticides; it uses the data in furtherance of the congressionally-created regulatory scheme. While other companies may obtain a registration on the basis of Monsanto's data, Section 3(c)(1)(D) does not afford those companies any other rights in this information. Nor are they entitled to examine the data under this subsection.

The district court reasoned (J.S. App. 31a-32a) that Section 3(c)(1)(D) completely destroys Monsanto's "fundamental right * * * to exclude" others from its property and, therefore, that a taking had been established. But this Court has unequivocally held that interference with the right to exclude does not by itself constitute a taking. *Pruneyard Shopping Center* v. *Robins*, 447 U.S. 74, 84 (1980). The "right to exclude" is merely one "strand" in Monsanto's "bundle" of rights. As the district court recognized, Monsanto retains significant rights in its data (J.S. App. 18a, 21a, 23a). First, Monsanto used its data to obtain valuable registrations for its products and Section 3(c)(1)(D) does not interfere with its continuing right to market those products. Second, Monsanto retains the right to exploit the data to develop new products or new uses for old products and to obtain domestic or foreign registrations for them (J.S. App. 18a, 21a; J.A. 212). Third, Monsanto retains the right to use the data outside the registration process for purposes such as advertising and marketing its products, defending claims against its products, and enhancing its reputation in the agricultural and scientific communities (J.S. App. 21a, 23a; J.A. 77, 209-212; Tr. 268-269). Since Monsanto has not lost these significant rights in its data, the limited interference Congress has mandated does not con-

stitute a taking. *Pruneyard Shopping Center* v. *Robins*, 447 U.S. at 84; *Andrus* v. *Allard*, 444 U.S. at 65-66.[26]

Other factors also show that the economic impact on Monsanto is not so substantial as to warrant a conclusion that the statute takes its property. The value of Monsanto's "right to exclude" is in reality only an element of the competitive position Monsanto enjoys in the marketplace. It is therefore appropriate to assess the impact of the statute on the entire range of competitive advantages Monsanto enjoys. On this score, the interference is not nearly so devastating as Monsanto asserts. The district court concluded that the company retains its primary sources of competitive advantage, including its product and use patents, its advertising and marketing techniques, and lead-time advantages not related to the exclusive use or secrecy of data (J.S. App. 18a-21a, 23a; J.A. 93, 102, 106-108, 136-137, 159-160, 164-165, 188-189, 204-206, 209-210).

Moreover, companies like Monsanto won from Congress a measure of protection for their data and the competitive advantage that the information may provide. Monsanto retains a 10-year exclusive use period for data submitted on any new active ingredient registered after 1978 and is entitled to compensation for use of other data submitted after 1969 for a 15-year period. These valuable replacement rights mitigate the burden of government action and militate strongly against a conclusion of a taking. *Penn Central*, 438 U.S. at 137. An additional benefit that Monsanto gains under the the statute is the reciprocal right to rely on its competitors' data to obtain registrations and to enter the market with a particular pesticide product. The statute thus "secures an average reciprocity of advantage" and may be sustained on this basis as well. *Pennsylvania Coal Co.* v. *Mahon*, 260 U.S. 393, 415 (1922).

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[26] See Gannon, *FIFRA and the "Taking" of Trade Secrets*, 8 B. C. Envtl. Aff. L. Rev. 593, 632-636 (1980).

It is clear from this survey that the principal competitive impact of the data consideration provisions is to reduce barriers to entry by allowing subsequent applicants to obtain registrations for products not covered by patents without duplicating test data EPA already has in its possession. This procompetitive impulse is, of course, precisely what Congress intended and is fully consonant with the purpose of the patent laws to foster competitive imitation once the 17-year period of exclusivity has expired. It is not unexpected that such an increase in competition will affect the market position of an innovator who had enjoyed a statutory monopoly, and may lead to reduced profits. But, "loss of future profits—unaccompained by any physical property restriction—provides a slender reed upon which to rest a takings claim." *Andrus* v. *Allard*, 444 U.S. at 66.

2. *The data disclosure provisions*

Similarly, the limited interference, if any, with Monsanto's use of its data that is attributable to the data disclosure provisions does not constitute a taking. What is at issue here is only the disclosure of health and safety data to certain classes of persons. Section 10 prevents, except in limited circumstances, the disclosure of a company's confidential product formulas and information about manufacturing and quality control processes. 7 U.S.C. 136h(d)(1)(A), (B), and (C). Moreover, Section 10(g) prohibits the knowing disclosure of *any information* to foreign or multinational businesses engaged in pesticide production or marketing. 7 U.S.C. 136h(g).[27] Nor does the fact of disclosure by itself place Monsanto at a competitive disadvantage in relation to other applicants for registration since the data consideration provisions permit EPA to rely on Monsanto's data to issue other registrations without the applicant having seen the data.

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[27] The district court found that most, if not all, of the large firms that do research and testing on pesticides are engaged in foreign or multinational pesticide marketing (J.S. App. 4a; J.A. 208).

Moreover, Monsanto retains other significant rights to exploit the data that do not depend on the continued confidentiality of the information. As the district court concluded (J.S. App. 21a), Monsanto developed the data primarily to obtain pesticide registrations, which are commercially valuable marketing licenses. Disclosure of data does not affect the continuation of Monsanto's registrations; nor does it prevent the company from using previously submitted data to obtain registration for new products or new uses for approved products. Indeed, as noted, see page 34, *supra*, Monsanto's research and development efforts have accelerated, rather than diminished, since the passage of the 1978 Amendments.

Monsanto simply has not made out a case of substantial and particularized interference with its interest in maintaining the secrecy of health and safety data that were submitted to the federal government. The public interest served by this provision, on the other hand, is quite substantial. Congress found here an overriding public policy to promote knowledge about the safety and efficacy of pesticide products, many of which are inherently dangerous. See page 34, *supra*. In addition to permitting members of the public to evaluate and adjust their own exposure to pesticides, the disclosure provisions also allow the public to stand on the same footing as the agency and the industry in proceedings under the statute. This Court has recognized the propriety and, indeed, the desirability of obtaining public input by making information on regulatory decisions available to the public. See, *e.g.*, *FCC* v. *Schreiber*, 381 U.S. 279 (1965); *Utah Fuel Co.* v. *National Bituminous Coal Comm'n*, 306 U.S. 56, 60-62 (1939).

The district court's contrary conclusion was based on its determination that the product label and the registration provide all the protection and information the public needs. The courts, however, are not at liberty to dismiss so cavalierly the contrary conclusions of Congress. *Hodel* v. *Indiana*, 452 U.S. at 326. Moreover, the district court

was wrong. Neither the fact of registration nor the label provides all the information necessary for persons who use or are exposed to pesticides to evaluate fully their safety in particular applications. Cf. *Federal Security Administrator* v. *Quaker Oats Co.*, 318 U.S. 218, 229-231 (1943).

Furthermore, this Court's decisions have long-since established the basic proposition that there is a legitimate public interest in requiring disclosure of trade secrets or proprietary information for the benefit of consumers that will defeat a taking claim. The Court has sustained a state statute, designed to foster agriculture within the state, that required the disclosure of the proportions of ingredients in a fertilizer mixture, *National Fertilizer Association* v. *Bradley*, 301 U.S. 178, 182 (1937), and has approved a similar requirement to disclose the ingredients of table syrup. *Corn Products Refining Co.* v. *Eddy*, 249 U.S. 427, 431 (1919). In rejecting claims that these statutory disclosure provisions unlawfully deprived companies of property, the Court declared in language fully applicable here that (249 U.S. at 431-432):

> it is too plain for argument that a manufacturer or vendor has no constitutional right to sell goods without giving to the purchaser fair information of what it is that is being sold. The right of a manufacturer to maintain secrecy as to his compounds and processes must be held subject to the right of the State, in the exercise of its police power and in the promotion of fair dealings, to require that the nature of the product be fairly set forth.[28]

Monsanto has not demonstrated that the balance Congress struck between the interest in secrecy and the public's right to be informed of the risks inherent in pesticides was so destructive of its expectations that it may escape the rule of *Corn Products* and *National Fertilizers Asso-*

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[28] See 301 U.S. at 182.

ciation.[29] Although Congress has made a limited adjustment in Monsanto's rights regarding the data, the company must bear that burden in exchange for " 'the advantage of living and doing business in a civilized community.' " *Andrus* v. *Allard*, 444 U.S. at 67 (quoting *Pennsylvania Coal Co.* v. *Mahon*, 260 U.S. 393, 422 (1922) (Brandeis, J., dissenting)).

III. EVEN IF FIFRA'S DATA CONSIDERATION AND DISCLOSURE PROVISIONS TAKE MONSANTO'S PROPERTY, THE DISTRICT COURT ERRED IN GRANTING INJUNCTIVE RELIEF

As we have shown, Sections 3(a)(1)(D) and 10 do not cause a "taking" of Monsanto's property. But even if the district court's contrary conclusion were correct, Monsanto would not be entitled to injunctive relief. A taking

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[29] A similar balance has been struck in a great number of federal statutes that authorize or require public disclosure of information submitted by private firms to the government. We have already referred (pages 20-21, *supra*) to federal statutes that require firms seeking to engage in regulated activity to disclose data they might otherwise choose not to reveal. In addition, many federal statutes provide for disclosure of allegedly "trade secret" information concerning potential hazards to public health. For example, notwithstanding trade secrecy claims, the Toxic Substances Control Act requires public disclosure of "health and safety data" concerning chemical substances and mixtures distributed in commerce (except for manufacturing processes and some formula information), 15 U.S.C. 2613(b); the Clean Air Act requires disclosure of "emission data," 42 U.S.C. (Supp. V) 7607(a)(1); the Federal Water Pollution Control Act requires disclosure of "effluent data," 33 U.S.C. 1318(b); and the Safe Drinking Water Act requires disclosure of all data concerning drinking water contaminants, 42 U.S.C. 300j-4(d). See also 42 U.S.C. 263g(d), requiring disclosure of trade secret data concerning radiation emissions from electronic products such as microwave ovens; 42 U.S.C. 5413(c)(5), requiring disclosure of trade secret data concerning safety-related defects in mobile homes; 46 U.S.C. 1464(d), authorizing disclosure of trade secret information regarding safety defects in boats and boating equipment; and 15 U.S.C. 2217, authorizing trade secret fire protection information to be disclosed when "necessary in order to protect health and safety."

of private property may not be enjoined as unconstitutional if the taking has been duly authorized, if it serves a public purpose, and if the owner will be able to receive just compensation for the property taken. See, *e.g.*, *Duke Power Co.* v. *Carolina Environmental Study Group, Inc.*, 438 U.S. 59, 94 n.39 (1978); *Regional Rail Reorganization Act Cases*, 419 U.S. 102, 126-127 and n.16 (1974); *Larson* v. *Domestic & Foreign Commerce Corp.*, 337 U.S. 682, 697 n.18 (1949). In this case, all three of these conditions are satisfied.

It is not disputed that EPA's consideration and disclosure of Monsanto's data are duly authorized by Sections 3(c)(1)(D) and 10. Moreover, as we have shown, pages 20-27, *supra*, both sections serve important public purposes. Thus, the only remaining issue is whether just compensation will be provided. As we will discuss, the statute provides some measure of compensation under the data consideration provisions. In addition, the Tucker Act, 28 U.S.C. 1491, provides Monsanto the means to obtain whatever additional just compensation is due for any "taking." See *Chevron Chemical Co.* v. *Costle*, 499 F. Supp. at 742-743. See also *Union Carbide Agricultural Products Co.* v. *Costle*, 632 F.2d at 1019; *Dow Chemical Corp.* v. *Costle*, 464 F. Supp. 395, 399 (E.D. Mich. 1978).

The district court erred in holding that Congress withdrew the Tucker Act remedy when it enacted FIFRA. The dispositive inquiry is "not whether the [challenged statute] expresses an affirmative showing of congressional intent to permit recourse to a Tucker Act remedy * * *," but rather whether Congress has "*withdrawn* the Tucker Act grant of jurisdiction to the Court of Claims to hear a suit involving the [challenged statute] 'founded . . . upon the Constitution.'" *Regional Rail Reorganization Act Cases*, 419 U.S. at 126 (emphasis in original). This rule of construction is based on the general principle that "*whether or not the United States so intended*," a taking claim is one "founded upon the Constitution" within the meaning of the Tucker Act and therefore within the Claims Court's jurisdiction. 419 U.S. at 126 (emphasis

supplied); *United States* v. *Causby*, 328 U.S. 256, 267 (1946). As this Court stated in *Yearsley* v. *W.A. Ross Construction Co.*, 309 U.S. 18, 21 (1940):

> [I]f the authorized action * * * does constitute a taking of property for which there must be just compensation under the Fifth Amendment, the Government has impliedly promised to pay that compensation and has afforded a remedy for its recovery by suit in the Court of Claims.

In this case, there is no indication in the statute or its history that Congress intended to impair the jurisdiction of the Claims Court by withdrawing the Tucker Act remedy. No language in FIFRA amends the Tucker Act, or otherwise purports to deny the liability of the United States. There is no discussion in the legislative history indicating that Congress thought any taking under the Fifth Amendment would occur, much less that the United States should curtail the waiver of its sovereign immunity against compensation claims.[30]

The district court mistakenly relied on the statute's creation of a procedure for original data submitters to obtain compensation from subsequent applicants. It is certainly not a necessary inference from this statutory mechanism for spreading among private parties the cost of testing pesticides that Congress also intended to extinguish any claims against the United States. To be sure,

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[30] Monsanto has relied on a floor statement of Senator Leahy containing the phrase "just compensation." 123 Cong. Rec. 25709 (1977) (Mot. to Aff. 26). The statement contains no reference to the Fifth Amendment or the Tucker Act and appears to represent nothing more than the Senator's view that compensation awarded under the arbitration scheme should be fair and reasonable. Moreover, this issue had been raised in litigation under the 1972 and 1975 Amendments. In 1976, well before the consideration and passage of the 1978 Amendments, one district court had denied a preliminary injunction on a taking claim because of its determination that the Tucker Act remedy had not been withdrawn. *Dow Chemical Corp.* v. *Train*, 423 F. Supp. 1359, 1364 (E.D. Mich. 1976).

Congress provided for what it thought was an appropriate reward for the use of a company's health and safety data. But that fact does not support a conclusion that Congress also blocked a company's recourse for losses for which the Constitution requires compensation and which were not fully offset by the amounts awarded under the statutory compensation scheme. *Regional Rail Reorganization Act Cases*, *supra*; *Pennsylvania* v. *ICC*, 535 F.2d 91, 97-98 (D.C. Cir. 1976).

This Court considered a similar situation in the *Regional Rail Reorganization Act Cases*, *supra*. There Congress had sought to solve a major rail transportation crisis by reorganizing several major railroads into a single system operated by a private, state-incorporated entity. 419 U.S. at 108-111. As part of this plan, certain rail properties were to be transferred to the new corporation. Congress explicitly recognized that the Fifth Amendment would require just compensation for this transfer and provided for compensation in the form of securities of the new corporation, certain government-backed obligations and other benefits. 419 U.S. at 111. In disposing of a claim that the resulting compensation would not meet the constitutional minimum, this Court concluded that Congress's express consideration of and provision for compensation due under the Fifth Amendment did not support an inference that it had withdrawn the remedy under the Tucker Act to make up any constitutional shortfall in the statutory compensation. 419 U.S. at 128-131. In the instant case, the support for such an inference is even weaker because Congress did not expressly consider any question of compensation due under the Fifth Amendment.[31] Thus, even if the data disclosure

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[31] The district court's other reasons for finding a congressional intent to foreclose relief under the Tucker Act are also without merit. It is of no significance that no monies were allocated for compensation (see J.S. App. 36a). Such an appropriation is not customary and is not a prerequisite to jurisdiction of the Claims Court under the Tucker Act. See *Yearsley* v. *W.A. Ross Constr.*

and consideration provisions do work a "taking" of Monsanto's property, it was erroneous for the district court to enjoin their implementation as unconstitutional—at least in the absence of willingness by the United States as a litigant to have the statutory scheme enjoined rather than to provide by means of the Tucker Act remedy whatever compensation is constitutionally required. *Regional Rail Reorganization Act Cases*, 419 U.S. at 102; *Chevron Chemical Co.* v. *Costle*, 499 F. Supp. at 742-743.

IV. THE CONSTITUTIONAL CHALLENGES TO THE ARBITRATION AND COMPENSATION SCHEME ARE NOT RIPE FOR RESOLUTION AND IN ANY EVENT ARE WITHOUT MERIT

A. The district court erred in considering Monsanto's constitutional attacks on the arbitration and compensation scheme in Section 3(c)(1)(D)(ii)

In addition to holding that the statute unconstitutionally takes Monsanto's property, the district court invalidated the arbitration and compensation scheme provided for in Section 3(c)(1)(D)(ii). Since Congress determined that health and safety testing data need be submitted only once for a particular pesticide, that provision was intended to allocate the costs of performing the tests among all companies who seek to have EPA consider the data in passing on registration applications. If a com-

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Co., 309 U.S. at 21 (in the case of a taking, the government impliedly promises to pay); *Hurley* v. *Kincaid*, 285 U.S. 95, 104 (1932) (compensation need not precede the taking). Finally, the district court's view (J.S. App. 36a) that the Tucker Act is not an adequate remedy because FIFRA works an "immediate taking of Monsanto's property as of the passage of the amendments to FIFRA" is unfounded. Obviously, if any taking occurs, it occurs only when EPA actually considers Monsanto's data to support another application or discloses the data. FIFRA itself does not automatically confiscate Monsanto's data. FIFRA merely provides for EPA's consideration and disclosure of the data under specified circumstances.

pany submits data for which the statute requires compensation, the firm that is seeking to have EPA consider the data must make an offer of compensation to the original submitter. 7 U.S.C. 136a(c)(1)(D)(ii). If the parties cannot agree on the amount of compensation, either party may initiate binding arbitration through the Federal Mediation and Conciliation Service. *Ibid.* The decision of the arbitrator is final and unreviewable except in the case of "fraud, misrepresentation, or other misconduct" by the parties or the arbitrator. *Ibid.* The district court concluded (J.S. App. 34a-36a) that this provision was invalid because: (1) it did not provide the constitutionally required just compensation; (2) it offended the Due Process Clause; and (3) it delegated judicial power to a non-Article III forum. The attack on this provision, however, was premature since Monsanto did not allege or establish that it had been injured by an actual arbitration under the statute. In these circumstances, the issues were not ripe for review.

Ripeness is a threshold element of Article III's requirement of a case or controversy. See *Duke Power Co.* v. *Carolina Environmental Study Group, Inc.*, 438 U.S. at 81; *Regional Rail Reorganization Act Cases*, 419 U.S. at 138. Accordingly, federal courts are without jurisdiction to adjudicate hypothetical disagreements or abstract claims before action has been taken that has a concrete effect on an aggrieved party. *Abbott Laboratories* v. *Gardner*, 387 U.S. 136, 148-149 (1967); *Toilet Goods Association* v. *Gardner*, 387 U.S. 158, 164 (1967). To determine if a question is ripe for review, the Court must consider the "fitness of the issues for judicial decision" and weigh that consideration against "the hardship to the parties of withholding court consideration." *Abbott Laboratories* v. *Gardner*, 387 U.S. at 149.

In this case, the asserted claims of unconstitutionality are premature in the absence of a specific arbitration award. The statute itself inflicts no harm on Monsanto. The company claims that the alleged defects in the statute

will prevent it from receiving the compensation that is due under the statute and the Constitution, but that conclusion depends entirely on the amount Monsanto may receive in any given case.[32] The matter is wholly speculative at present.[33] If the amount awarded to Monsanto in any future arbitration is satisfactory, there would be no occasion to decide whether the process comported with the Fifth Amendment or whether an Article III judge was required to make or review the award.

Precisely the same considerations led this Court to dismiss as premature a similar attack on a statutory requirement for binding arbitration. *Babbitt* v. *United Farm Workers Nat'l Union*, 442 U.S. 289, 304-305 (1979). In that case, an Arizona statute required binding arbitration of a labor dispute between farm workers and agricultural employers if there was a strike and if the employer responded by obtaining a temporary restraining order enjoining the strike. The Court held that so long as there was a possibility of settling such disputes through negotiation and without the need to invoke the challenged

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[32] Monsanto's claim that the arbitration procedure will not provide the just compensation required by the Fifth Amendment is precluded by the availability of the Tucker Act remedy. See pages 41-44, *supra*.

[33] Monsanto would suffer concrete injury only after a series of discrete, independent events. First, a company must apply for a registration and seek to rely on data submitted by Monsanto and compensable under Section 3(c)(1)(D). Second, that company must make a compensation offer to Monsanto. Third, EPA must decide to grant the registration. Fourth, Monsanto and the other company must fail to reach agreement on the amount of compensation. Fifth, arbitration must be initiated and the arbitrator must make an award. At any stage of such proceedings, Monsanto's statutory right to compensation may not mature or may be fully satisfied. It is apparent that no immediate injury is caused by the enactment of the statute and that such injury is not the inexorable result of the legislation. The existence of the many possible contingencies shows that the claimed injury is speculative and the issues presented hypothetical. See *Toilet Goods Association*, v. *Gardner*, 387 U.S. at 163-164.

arbitration procedures, "any ruling on the compulsory arbitration provision would be wholly advisory." 442 U.S. at 305.

In addition, there is no hardship to Monsanto in withholding judicial review at this time. If and when Monsanto receives an award that in its view is inadequate and illegal, the company may bring an action to challenge the award and present its constitutional claims in that proceeding.[34] The expense and inconvenience of pursuing the arbitration procedures and bringing an action in the district court is not the kind of hardship that would avoid a finding that the claim is currently premature. See *FTC* v. *Standard Oil Co.*, 449 U.S. 232, 234 (1980).

B. Neither the Due Process Clause nor Article III requires invalidation of the arbitration and compensation scheme

Even if Monsanto's claims were ripe for review, the district court erred on the merits. First, binding arbitration of statutorily created entitlements does not offend due process. *Hardware Dealers Mutual Fire Insurance Co.* v. *Glidden Co.*, 284 U.S. 151, 157-158 (1931) (state statute mandating arbitration of the amount of loss under insurance policy). See also *Andrews* v. *Louisville & N. RR.*, 406 U.S. 320, 322 (1972) (compulsory arbitration provision of the Railway Labor Act for minor disputes, 45 U.S.C. 153 First (i)). Nor do the statute's limitations on judicial review call for a different result. In *Crane* v. *Hahlo*, 258 U.S. 142 (1922), this Court upheld a statute that declared that compensation awards for

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[34] One such proceeding, not involving Monsanto, is currently pending in the United States District Court for the District of Columbia. *PPG Industries, Inc.* v. *Stauffer Chemical Co.*, C.A. No. 83-1941 (filed July 7, 1983). Plaintiff in that action has attacked Section 3(c)(1)(D) as unconstitutional under the Due Process Clause, the Taking Clause and Article III.

damage caused by municipal construction work were final and unreviewable. The Court concluded that as long as the process was efficient and the courts could remedy jurisdictional defects, fraud or willful misconduct of the board making the awards, the statute satisfied the Due Process Clause. 258 U.S. at 147-148. See *Edwards* v. *St. Louis-S.F. R.R.*, 361 F.2d 946, 955 (7th Cir. 1966). See also *Switchmen's Union* v. *National Mediation Board*, 320 U.S. 297, 300-301 (1943); *Ludwig Honold Mfg. Co.* v. *Fletcher*, 405 F.2d 1123, 1127-1128 (3d Cir. 1969).

There is no basis for the district court's further conclusion that the statute is unconstitutionally vague for failing to provide standards for determining the measure of compensation. The 1972 Amendments provided for the right to "reasonable compensation for providing the test data to be relied upon." § 3(c)(1)(D), 86 Stat. 980. The stated purpose was to spread the costs of data development (S. Rep. 92-838 (Pt. II), *supra*, at 69). The intended measure of compensation was plainly the equitable division of those costs. In 1978, Congress substantially altered the procedural aspects of the arbitration and compensation scheme, assigning the determination of the amount of compensation to the parties and the arbitrator rather than to EPA. See pages 12-13, *supra*. It is clear from the legislative history, however, that no change in the expected measure of compensation was intended. See S. Rep. 95-334, *supra*, at 7-8. Senator Leahy explained in floor debate that the scheme "protects the data developer's right to *recover his data generation costs* * * *." 123 Cong. Rec. 25706 (1977) (emphasis added). Contrary to the district court's conclusion, a constitutionally satisfactory measure for compensation under Section 3(c)(1)(D), the equitable division of data development costs, can be derived from the statute and its history.

Finally, it does not violate Article III of the Constitution to assign the resolution of a compensation dispute to an arbitrator whose decision is subject to limited judicial

review.[35] This Court has frequently upheld laws delegating the determination of statutorily-created rights to administrative bodies without any judicial review. See *South Carolina* v. *Katzenbach*, 383 U.S. 301, 333 (1966); *Switchmen's Union* v. *National Mediation Board*, 320 U.S. at 300-301, 303. See also *Andrews* v. *Louisville & N. R.R.*, *supra*; *Crane* v. *Hahlo*, *supra*.[36]

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[35] This Court's recent decision in *Northern Pipeline Construction Co.* v. *Marathon Pipe Line Co.*, 458 U.S. 50 (1982), is not to the contrary. The vice of the 1978 Bankruptcy Act was the assignment to the bankruptcy courts of the authority to adjudicate traditional common law rights (*id.* at 81-86); the challenged provisions of FIFRA deal only with a statutorily-created right of recent vintage. Indeed, the plurality in *Northern Pipeline* reaffirmed Congress's constitutional authority to proceed in this manner (*id.* at 83 (footnote omitted)):

> [W]hen Congress creates a statutory right, it clearly has the discretion, in defining that right, to create presumptions, or assign burdens of proof, or prescribe remedies; it may also provide that persons seeking to vindicate that right must do so before particularized tribunals created to perform the specialized adjudicative tasks related to that right.

Thus, both the court below and the district court in *Union Carbide Agricultural Products Co.* v. *Ruckelshaus*, 571 F. Supp. 117 (S.D. N.Y. 1983), erred in relying on *Northern Pipeline* to strike down the arbitration provision.

[36] Moreover, even if this Court were to resolve the Article III issue in Monsanto's favor, that would not justify enjoining the entirety of Section 3(c)(1)(D), but only the limitation on judicial review contained in the fourth sentence of Section 3(c)(1)(D)(ii). See 2 C. Sands, *Statutes and Statutory Construction* § 44.04 (4th ed. 1973); 7 U.S.C. 136x (severability). In this respect, the judgment entered on November 29, 1983 in *Union Carbide Agricultural Products Co.* v. *Ruckelshaus*, *supra*, was too broad since it barred EPA from considering any data that would be subject to the arbitration provisions in Section 3(c)(1)(D)(ii).

CONCLUSION

The judgment of the district court should be reversed and the case remanded with instructions to vacate the injunction and to dismiss the complaint.

Respectfully submitted.

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